HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Refer to: FEI 3002830716

Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2307

November 17, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jeffery J. Burdick, President
The Deli, Inc.
593 S. Birdneck Road
Virginia Beach, Virginia 23451

Dear Mr. Burdick:

During a Food and Drug Administration (FDA) inspection of your seafood sandwich processing facility located at 593 S. Birdneck Road, Virginia Beach, Virginia, conducted November 1, 2000, our investigator observed serious deviations from Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) Fish and Fishery Products (Seafood HACCP) regulations and insanitary conditions as a result of your failure to follow the Good Manufacturing Practice (GMP) regulations for food firms (21 CFR Part 110). These deviations and insanitary conditions cause your ready-to-eat tuna fish salad sandwiches to be in violation of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

The deviations were as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for tuna fish salad sandwiches to control the food safety hazard of pathogen growth and toxin formation as a result of time/temperature abuse.

2. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). Your firm did not monitor the cleanliness of food contact surfaces and the prevention of cross-contamination from insanitary objects to ensure control, as evidenced by:

   - An accumulation of old food residue was observed on the underside of the sandwich conveyor belt.

   - A handheld bristle broom was observed being used to clean the blade of the sandwich-slicing machine.

Of particular concern to the FDA is the fact that similar deviations were brought to your attention in our letter dated February 29, 2000.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. We may take further regulatory action if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations (21 CFR 123), and the food GMPs (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please respond in writing within 15 working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as a copy of your HACCP plan to control pathogen growth and toxin formation, sanitation monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, at 10710 Midlothian Turnpike, Suite 424, Richmond, VA 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire may be reached at 804-379-1627, extension 14.

Sincerely,

Monica Brown-Reid

for Lee Bowers
Director, Baltimore District

cc: Virginia Department of Agriculture
and Consumer Services
Division of Consumer Protection
Office of Dairy and Food
1100 Bank Street, Suite 510
Richmond, Virginia 23219